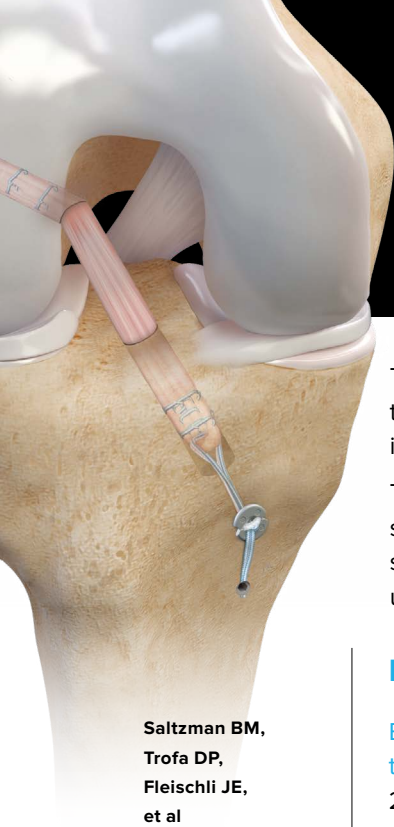


ACL Backup Fixation Scientific Update



Saltzman BM,
Trofa DP,
Fleischli JE,
et al

The ACL Backup Fixation System includes the implants and instruments needed to back up the fixation sutures of an ACL graft or FiberTape® suture for the *Internal/Brace*™ technique used in an ACL reconstruction or primary repair.

The SwiveLock® anchor is a simple, low-profile option for ACL backup fixation and comes self contained in an all-inclusive ACL Backup Kit, containing a 4.75 mm SwiveLock implant, a spade-tipped drill, and 2 disposable taps (4.75 mm and 5.2 mm for hard bone or when using FiberTape® suture).

In Vitro Studies: Biomechanical Validation

[Biomechanical comparison of tibial-sided supplemental fixation techniques in bone-patellar tendon-bone anterior cruciate ligament reconstruction \[published online Jan 11, 2023\].](#) *Knee.* 2023;41:66-71. doi:10.1016/j.knee.2022.12.005

- This study was a biomechanical comparison of secondary graft fixations using a post and washer compared to a SwiveLock anchor in the setting of a BTB ACL reconstruction.
- 16 cadaveric human tibias were prepared with anatomic, 10 mm-diameter ACL reconstruction tunnels. BTB grafts with 10 mm × 25 mm bone plugs were fixated in the tibias using 9 mm × 20 mm BioComposite FastThread™ interference screws with femoral side of the graft affixed to a loading apparatus oriented vertically in line with the tibial tunnel to create “worst case scenario” loading.
- Secondary fixation was achieved by fixating the tibial-sided graft sutures 1 cm below the tibial tunnel using either a unicortical 6.5 mm × 25 mm cancellous screw and washer (8) or 4.75 mm PEEK SwiveLock anchors (8).
- The SwiveLock constructs demonstrated a higher mean stiffness than the post constructs. Both constructs demonstrated similar performance with respect to all biomechanical parameters assessed including yield strength and ultimate strength. However, of the 8 original specimens in each group, 1 of 8 suture anchor specimens (12.5%) and 6 of 8 metallic screw post specimens (75%) failed during cyclical testing and were unable to undergo displacement and load-to-failure testing.

[A comparison between a retrograde interference screw, suture button, and combined fixation on the tibial side in an all-inside anterior cruciate ligament reconstruction: a biomechanical study in a porcine model.](#) *Am J Sports Med.* 2009;37(1):160-167. doi:10.1177/0363546508323747

- 18 porcine tibias and 18 bovine extensor tendon allografts were divided into 3 groups: retrograde absorbable screw fixation, cortical-cancellous suture button suspension apparatus fixation, and combined tibial fixation in the tibia with 6 specimens per group
- Specimens were biomechanically tested with cyclic (500 cycles, 50 N-250 N, 1 Hz) and load-to-failure (20 mm/min) parameters.
- Results: Soft-tissue grafts fixed with a combination of a retrograde screw and a suture button were able to withstand higher initial failure and ultimate failure loads and were also stiffer than grafts fixed with either a retrograde screw or a suture button alone.

Walsh MP,
Wijdicks CA,
Parker JB,
Hapa O,
LaPrade RF

The *Internal/Brace* surgical technique is intended only to augment the primary repair/reconstruction by expanding the area of tissue approximation during the healing period and is not intended as a replacement for the native ligament. The *Internal/Brace* technique is for use during soft tissue-to-bone fixation procedures and is not cleared for bone-to-bone fixation.



Vopat B,
Paller D,
Machan JT,
et al

[Effectiveness of low-profile supplemental fixation in anterior cruciate ligament reconstructions with decreased bone mineral density.](#) *Arthroscopy*. 2013;29(9):1540-1545. doi:10.1016/j.arthro.2013.05.019

- This study compared ACL fixation using a bioabsorbable interference screw and a supplemental low-profile suture anchor (4.5 mm PushLock® anchor) with a standard bioabsorbable interference screw to determine if fixation methods were dependent on tibial bone mineral density.
- A bone mineral density scanner was used in 20 fresh frozen female knee specimens. The specimens were divided into 2 groups—1 with just the interference screw and 1 with the screw and PushLock anchor combined. Tibial-sided ACL fixation with hamstring tendon grafts were performed on all specimens. Load-to-failure and stiffness were biomechanically tested.
- Results: Supplemental fixation of ACL with a PushLock anchor is beneficial in persons with normal bone mineral density of the proximal tibia.

Tetsumura S,
Fujita A,
Nakajima M,
Abe M

[Biomechanical comparison of different fixation methods on the tibial side in anterior cruciate ligament reconstruction: a biomechanical study in porcine tibial bone.](#) *J Orthop Sci*. 2006;11(3):278-282. doi:10.1007/s00776-006-1016-y

- The purpose of this study was to compare the biomechanical characteristics of 4 types of ACL reconstruction methods on the tibial side.
- 28 porcine tibias were divided into 4 groups based on different fixation methods. Group D was fixed using a double-spike plate (DSP), Group I was fixed using an interference screw, Group DI-80 was fixed using both an interference screw and DSP (80 N tension was applied to DSP), and Group DI-150 was fixed using both an interference screw and DSP (150 N tension was applied to DSP).
- Results demonstrate that the initial fixation strength of the hamstring tendon can be increased by using an interference screw combined with DSP on the tibial side.

Yoo JC,
Ahn JH,
Kim JH,
et al

[Biomechanical testing of hybrid hamstring graft tibial fixation in anterior cruciate ligament reconstruction.](#) *Knee*. 2006;13(6):455-459. doi:10.1016/j.knee.2006.08.001

- The purpose of this study was to compare the biomechanical characteristics of quadrupled hamstring graft tibial fixation using 3 different fixation methods. 9 matched pairs (18 specimens) of cadaver tibias were divided into 3 groups of 6 specimens.
- The first group was fixed with only a tapered 30 mm bioabsorbable screw (BIS), the second group was fixed first with a BIS, and then the remaining tendon portion was additionally fixed with a titanium cortical screw and spike washer, and the third group was fixed with only a cortical screw and spike washer.
- Biomechanical testing with cadavers showed that a BIS and additional cortical screw and spike washer fixation to the distal hamstring tendon resulted in higher load at failure and stiffness compared to either BIS or cortical screw and spike washer fixation alone.



Kim MK,
Na SI,
Lee JM,
Park JY

[Comparison of bioabsorbable suture anchor fixation on the tibial side for anterior cruciate ligament reconstruction using free soft tissue graft: experimental laboratory study on porcine bone.](#) *Yonsei Med J.* 2014;55(3):760-765. doi:10.3349/ymj.2014.55.3.760

- Additional tibial fixation is essential for aggressive rehabilitation. Authors hypothesized that additional graft tissue fixation using bioabsorbable suture anchors would provide sufficient pullout strength.
- 24 fresh frozen porcine distal femur and patellar tendon preparations were used. All specimens were divided into 3 groups based on additional fixation methods: (A) isolated BIS; (B) BIS and bioabsorbable suture anchor (BSA); and (C) BIS and post cortical screw. Tensile testing was carried out under an axial load. Ultimate failure load and ultimate failure load after cyclic loading were recorded.
- Conclusion: An additional BSA fixation resulted in a significantly higher ultimate failure load and stiffness than isolated BIS fixation and similar to post screw fixation.

Noonan BC,
Bachmaier S,
Wijdicks CA,
Bedi A

[Independent suture tape reinforcement of tripled smaller-diameter and quadrupled grafts for anterior cruciate ligament reconstruction with tibial screw fixation: a biomechanical full construct model.](#) *Arthroscopy.* 2020;36(2):481-489. doi:10.1016/j.arthro.2019.06.036

- This study compared the effect of independent suture tape reinforcement on the dynamic elongation and stiffness behavior as well as ultimate strength of tripled smaller diameter and quadrupled soft-tissue grafts for ACL reconstruction (ACLR) with tibial screw fixation in a biomechanical in vitro study.
- Tripled smaller diameter (8 mm) and quadrupled (9 mm) bovine tendon grafts with and without suture tape reinforcement (n = 8 in each group) were tested using femoral suspensory and tibial interference screw fixation. The suture tape was femoral sided and fixed independent from the graft by passing it through the suspensory button and securing the 2 open tibial strands with a secondary interference screw.
- Reinforcement of tripled and quadrupled grafts substantially decreased total elongation by 56%. No statistical significance was found between the reinforced groups.
- Independent reinforcement of soft-tissue grafts with suture tape strengthened the performance, especially of tripled smaller diameter grafts for ACLR with tibial screw fixation by significantly improving dynamic elongation at increased stiffness and ultimate strength. Quadrupled reinforced grafts showed no overconstraining and structurally behaved similarly to tripled grafts with reinforcement.

Verioti CA,
Sardelli MC,
Nguyen T

[Evaluation of 3 fixation devices for tibial-sided anterior cruciate ligament graft backup fixation.](#) *Am J Orthop.* 2015;44(7):E225-E230.

- This study biomechanically evaluated 30 porcine tibias with 3 methods of tibial-sided fixation for ACLR: a fully threaded interference screw only, an interference screw with 4.5 mm bicortical post, and an interference screw with a 4.75 mm SwiveLock® anchor.
- Mechanical testing consisted of 500 cycles between 50 N and 250 N at 1 Hz followed by a pull-to-failure conducted at 20 mm/minute.
- Ultimate load-to-failure testing demonstrated the largest mean (SD) load tolerated in the post/washer group, 1148 (186) N compared to the SwiveLock anchor group, 1007 (176) N, and the screw-only group, 778 (139) N. There was no statistical difference between the 2 backup fixation groups.
- Conclusion: Use of a SwiveLock anchor as backup fixation at the tibial side in soft-tissue ACLR is a safe, effective alternative to a bicortical post and provides statistically equivalent pullout strength with unlikely requirement for future hardware removal.



Hill PF,
Russell VJ,
Salmon LJ,
Pinczewski LA

In Vivo Studies: Clinical Outcomes

The influence of supplementary tibial fixation on laxity measurements after anterior cruciate ligament reconstruction with hamstring tendons in female patients. *Am J Sports Med.* 2005;33(1):94-101. doi:10.1177/0363546504268036

- This was a randomized controlled clinical trial in which 56 female patients divided into 2 groups (standard tibial fixation with 7 mm × 25 mm metal interference screw versus metal interference screw with supplementary staple fixation) were followed for 2 years.
- After 2 years, the mean side-to-side difference using KT-1000 arthrometer manual maximum measurements was 1.8 mm (standard group) and 1.1 mm (staple group).
- Conclusions: Supplementary tibial fixation in female patients undergoing ACLR with hamstring tendon graft in addition to a single-size screw significantly improves laxity measurements and clinical stability assessment 2 years after surgery.

Janjić NJ,
Dulić O,
Ninković S,
Harhaji V,
Gojković Z,
Milankov M

Functional performance test after anterior cruciate ligament reconstruction with hybrid tibial fixation. *Med Pr.* 2016;69(1):59-66. doi.org/10.2298/MPNS16S1059J

- 90 patients who underwent ACLR were randomly divided into 3 groups: (1) patients with standard single-bundled hamstring tendon graft and standard operative technique, (2) patients had a modified single-bundle hamstring tendon graft with bone attachments, and (3) patients were operated with hybrid fixation technique at the tibial site.
- Group 3 patients achieved statistically significant better postoperative results on the Tegner scale and Lysholm scores when compared to patients in Groups 1 and 2. It took the third group athletes a significantly shorter time to participate in the first competition after surgery than the athletes from the other 2 groups.
- Conclusion: Hybrid operative technique increased strength and stability of the graft at the tibial site which accelerated healing process and reduced knee laxity.

Bodendorfer BM,
Michaelson EM,
Shu HT,
et al

Suture augmented versus standard anterior cruciate ligament reconstruction: a matched comparative analysis. *Arthroscopy.* 2019;35(7):2114-2122. doi:10.1016/j.arthro.2019.01.054

- This study compared outcomes between standard ACLR using hamstring grafts with and without suture augmentation (SA). Patients who underwent ACLR with hamstring autografts or allografts with minimum 2-year follow-up were retrospectively reviewed.
- 60 patients who underwent ACLR with hamstring autografts or allografts with minimum 2-year follow-up were retrospectively reviewed. The suture-augmented group used a TightRope® ABS tibial fixation button with a 4.75 mm SwiveLock® ACL anchor backup.
- The study demonstrates that suture-augmented hamstring ACLRs were associated with improved PROMs, less pain, and a higher percentage of and earlier return to preinjury activity level when compared with standard hamstring ACLRs.



Balazs GC,
Brelin AM,
Grimm PD,
Dickens JF,
Keblish DJ,
Rue JH

Systematic Reviews

[Hybrid tibia fixation of soft-tissue grafts in anterior cruciate ligament reconstruction: a systematic review.](#) *Am J Sports Med.* 2016;44(10):2724-2732. doi:10.1177/0363546515621541

- This was a total of 21 studies (15 biomechanical and 6 clinical).
- Most biomechanical studies reported significantly increased strength and stiffness with hybrid fixation versus single modes of fixation. Among clinical studies, 66% reported significantly decreased anterior-posterior laxity when hybrid fixation methods were employed with the remainder showing no difference.
- Conclusion: Hybrid methods of tibial-sided graft fixation in ACLR result in stronger initial fixation and less side-to-side laxity after healing but do not change patient-reported outcomes at 1- to 3-year follow-up.

Surgical Technique Citations

[A low-profile method of hybrid tibial fixation for soft tissue grafts in anterior cruciate ligament reconstruction.](#) *Orthopedics.* 2009;32(4):orthosupersite.com/view.asp?rID=38351. doi.org/10.3928/01477447-20090401-01

- This article introduces a low-profile technique for ACLR using an interference screw and knotless anchor. Biomechanically, this technique has a significantly a greater load-to-failure than interference screw fixation alone.
- Describes the technique for ACLR using an Achilles tendon allograft with bone plug combined with ACL backup.

Coleman S,
Gallo R,
Kompel J,
Purnell G,
Altman G